

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

ROLLIN TOMLIN,	:	
Plaintiff,	:	
v.	:	Case No. 3:19-cv-354
SMITH & NEPHEW, INC., <i>et al.</i> ,	:	JUDGE WALTER H. RICE
Defendants.	:	

DECISION AND ENTRY SUSTAINING IN PART AND OVERRULING
IN PART DEFENDANT SMITH & NEPHEW, INC.'S MOTION TO
DISMISS PLAINTIFF'S COMPLAINT (DOC. #5); PLAINTIFF GIVEN
LEAVE TO AMEND COMPLAINT WITHIN 14 DAYS

Plaintiff Rollin Tomlin had a total knee replacement in 2015. His doctor used the Journey II Total Knee System, manufactured by Defendant Smith & Nephew, Inc. Plaintiff continued to suffer severe pain and discomfort, and had revision surgery in 2017. He then filed suit against Smith & Nephew, alleging numerous claims of product liability. This matter is currently before the Court on Defendant Smith & Nephew, Inc.'s Motion to Dismiss Plaintiff's Complaint, Doc. #5.

I. Background and Procedural History

On October 27, 2015, Rollin Tomlin underwent total knee arthroplasty. His doctor implanted the Journey II Total Knee System (hereafter the "Product"),

designed, manufactured and distributed by Defendant Smith & Nephew, Inc.

Tomlin continued to experience pain and discomfort in his knee. Two years later, he had revision surgery.

On October 16, 2019, Tomlin filed suit in the Montgomery County Common Pleas Court against Smith & Nephew, and against Doe Defendants 1-100. Smith & Nephew removed the case to federal court on the basis of diversity jurisdiction. Tomlin essentially argues that Smith & Nephew knew, or should have known, of problems with the Product that would cause the Product to loosen and fail. The Complaint asserts twelve causes of action:

- (I) Negligence
- (II) Ohio Product Liability Act ("OPLA") violations
- (III) Strict Products Liability: OPLA—Design Defect
- (IV) Strict Products Liability: OPLA—Manufacturing Defect
- (V) Strict Products Liability: OPLA—Failure to Warn
- (VI) Breach of Express Warranty
- (VII) Breach of Implied Warranty
- (VIII) Fraudulent Misrepresentation
- (IX) Fraudulent Concealment
- (X) Negligent Misrepresentation
- (XI) Unjust Enrichment
- (XII) Punitive Damages

Doc. #3.¹

Defendant has moved to dismiss the Complaint in its entirety. Doc. #5.

That motion is fully briefed, Docs. ##8, 9, and ripe for decision.

¹ As Defendant points out, the Counts are incorrectly numbered in the Complaint. There is no Count I or Count IX, but there are two each of Counts II and XI. The Court has taken the liberty of renumbering the Counts and will refer to them by their new numbers throughout this Decision and Entry.

II. Fed. R. Civ. P. 12(b)(6)

Federal Rule of Civil Procedure 8(a) provides that a complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” The complaint must provide the defendant with “fair notice of what the . . . claim is and the grounds upon which it rests.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

Federal Rule of Civil Procedure 12(b)(6) allows a party to move for dismissal of a complaint on the basis that it “fail[s] to state a claim upon which relief can be granted.” The moving party bears the burden of showing that the opposing party has failed to adequately state a claim for relief. *DirecTV, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007) (citing *Carver v. Bunch*, 946 F.2d 451, 454-55 (6th Cir. 1991)). The purpose of a motion to dismiss under Rule 12(b)(6) “is to allow a defendant to test whether, as a matter of law, the plaintiff is entitled to legal relief even if everything alleged in the complaint is true.” *Mayer v. Mylod*, 988 F.2d 635, 638 (6th Cir. 1993). In ruling on a 12(b)(6) motion, a court must “construe the complaint in the light most favorable to the plaintiff, accept its allegations as true, and draw all reasonable inferences in favor of the plaintiff.” *Handy-Clay v. City of Memphis*, 695 F.3d 531, 538 (6th Cir. 2012) (quoting *Treesh*, 487 F.3d at 476).

Nevertheless, to survive a motion to dismiss under Rule 12(b)(6), the complaint must contain “enough facts to state a claim to relief that is plausible on its face.” *Twombly*, 550 U.S. at 570. Unless the facts alleged show that the plaintiff’s claim crosses “the line from conceivable to plausible, [the] complaint

must be dismissed.” *Id.* Although this standard does not require “detailed factual allegations,” it does require more than “labels and conclusions” or “a formulaic recitation of the elements of a cause of action.” *Id.* at 555. “Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009). Legal conclusions “must be supported by factual allegations” that give rise to an inference that the defendant is, in fact, liable for the misconduct alleged. *Id.* at 679.

III. Analysis

Plaintiff seeks recovery under a wide variety of theories. However, as the Complaint states, “[e]ach and every one of Plaintiff’s claims for damages relate to Defendants’ design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of the Product.” Doc. #3, PageID#66.

A. OPLA Abrogates All Common Law Claims

Defendant argues that Plaintiff’s common law claims of negligence, breach of express warranty, breach of implied warranty, fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and unjust enrichment (Counts I and VI-XI) must be dismissed because they are expressly abrogated by the Ohio Products Liability Act (“OPLA”), Ohio Revised Code § 2307.71(B). That statute provides that “Sections 2307.71 to 2307.80 of the Revised Code are intended to abrogate all common law product liability claims or causes of action.” Ohio Rev. Code § 2307.71(B).

1. Negligence, Fraudulent Misrepresentation, Fraudulent Concealment, Unjust Enrichment (Count I, VIII, IX, XI)

By not responding to Defendant's argument, Plaintiff impliedly concedes that the claims for negligence, fraudulent misrepresentation, fraudulent concealment, and unjust enrichment are abrogated by the OPLA. *See Brown v. VHS of Michigan, Inc.*, 545 F. App'x 368, 372 (6th Cir. 2013) ("a plaintiff is deemed to have abandoned a claim when a plaintiff fails to address it in response to a motion."). On this basis, the Court SUSTAINS Defendant's Motion to Dismiss Counts I, VIII, IX and XI, and dismisses these Counts with prejudice.²

2. Breach of Express and Implied Warranty (Counts VI and VII)

Plaintiff concedes that his claims for breach of express and implied warranty are also subsumed by the OPLA. Nevertheless, he argues that, rather than dismiss these claims, the Court should grant him leave to amend his Complaint to assert these claims under Ohio Revised Code § 2307.77, the OPLA provision governing products defective due to nonconformance with manufacturers' representations.³

² Defendant also argues that the claims of fraudulent misrepresentation and fraudulent concealment must be dismissed because Plaintiff has failed to plead these claims with the particularity required by Fed. R. Civ. P. 9(b). Given the Court's finding that these claims are abrogated by the OPLA, the Court does not reach this other argument.

³ That statute provides that "[a] product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation." Ohio Rev. Code § 2307.77.

A plaintiff seeking to recover under § 2307.77 must prove:

- (1) that the manufacturer made a representation as to a material fact concerning the character or quality of the manufacturer's product;
- (2) that the product did not conform to that representation;
- (3) that the plaintiff justifiably relied on that representation; and
- (4) that the plaintiff's reliance on the representation was the direct and proximate cause of the plaintiff's injuries.

Gawloski v. Miller Brewing Co., 96 Ohio App. 3d 160, 165, 644 N.E.2d 731, 734 (1994).

Defendant argues that any such amendment would be futile because Plaintiff has not alleged sufficient facts indicating that the Product was defective or how it failed to conform to a representation made by Defendant. The Court rejects this argument. Plaintiff has alleged that Defendant expressly warranted that the Product was safe and effective, was of merchantable quality, that it had no dangerous side effects, and that it was adequately tested and fit for its intended use. He has further alleged that the Product did not conform to these representations in that it caused him serious injury, including severe pain and the need for revision surgery, that he and his physician justifiably relied on Defendant's representations, and that such reliance was the proximate cause of his injuries. Doc. #3, PageID##86-89.

Given that Plaintiff's common law claims of breach of express and implied warranty are abrogated by the OPLA, the Court SUSTAINS Defendant's Motion to Dismiss Counts VI and VII. Nevertheless, within 14 days of the date of this

Decision and Entry, Plaintiff may amend his Complaint to replead these two claims under the OPLA, mindful of the strictures of Fed. R. Civ. P. 11.

3. Negligent Misrepresentation (Count X)

In Count X of the Complaint, Plaintiff alleges that Defendant had a duty to tell the medical community, the FDA and consumers the truth about the safety and effectiveness of the Product, that Defendant breached this duty by intentionally concealing the truth and failing to warn about the defective condition of the Product, that he and his physician justifiably relied on Defendant's representations, and that he was injured as a result. Doc. #3, PageID##96-98. Defendant argues that this negligent misrepresentation claim is abrogated by the OPLA.

Citing *Hogue v. Pfizer, Inc.*, 893 F. Supp. 2d 914, 918 (S.D. Ohio 2012) (Watson, J.), *vacated in part on other grounds*, No. 2:10-cv-805, 2013 WL 12368615 (S.D. Ohio Sept. 5, 2013), Plaintiff argues that, although the OPLA abrogates negligent misrepresentation claims that are based on a failure to warn, it does not abrogate negligent misrepresentation claims that are based on active deception. He maintains that his claim involves active deception in that Defendant made false representations concerning the Product and failed to disclose material information concerning the Product's safety and effectiveness.

The Court disagrees. The essence of Plaintiff's claim is a failure to warn about the risks associated with the Product. As in *Hogue*, it is "based on a theory of omission and concealment." *Id.* at 919. It is, therefore, abrogated by the OPLA.

On this basis, the Court SUSTAINS Defendant's Motion to Dismiss Count X, the negligent misrepresentation claim, and dismisses this claim with prejudice.

B. OPLA Claims (Counts II, III, IV, V)

Plaintiff has asserted four claims under the OPLA: (1) Supplier Liability under Ohio Revised Code § 2307.78 (Count II); (2) Strict Liability for Design Defect under Ohio Revised Code § 2307.75 (Count III); (3) Strict Liability for Manufacturing Defect under Ohio Revised Code § 2307.74 (Count IV); and (4) Strict Liability for Failure to Warn under Ohio Revised Code § 2307.76 (Count V). Defendant argues that, under the pleading standards set forth in *Iqbal/Twombly*, Plaintiff has failed to state a claim upon which relief may be granted.

1. Supplier Liability (Count II)

Count II is broadly entitled "Ohio Product Liability Act Claims." As Defendant notes, it appears to encompass a variety of theories of liability, including negligence. Plaintiff alleges that Defendant failed to exercise reasonable care in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale and distribution of the Product. Doc. #3, PageID#71. As Defendant notes, these general allegations of negligence appear to be duplicative of other claims asserted in the Complaint. Plaintiff does not rebut this argument.

Count II, however, also alleges that Defendant is liable as a "supplier" of the Product under Ohio Revised Code § 2307.78(A)(2), because the Product did not

conform, when it left the control of Defendant, to representations made by Defendant, and because that representation and the failure to conform to it, were a proximate cause of Plaintiff's damages.

Plaintiff has alleged that Defendant is both a manufacturer and a supplier of the Product. Defendant correctly points out, however, that Plaintiff cannot proceed against a manufacturer under a theory of supplier liability. Ohio Revised Code § 2307.71(A)(15)(b)(i) states that a "supplier" does not include a "manufacturer." *See also Frey v. Novartis Pharm. Corp.*, 642 F. Supp. 2d 787, 795 (S.D. Ohio 2009) (Weber, J.) (holding that, because plaintiffs alleged that Novartis was the manufacturer, they could not proceed under a theory of supplier liability). On this basis, the Court SUSTAINS Defendant's Motion to Dismiss Count II, and dismisses that claim with prejudice.

2. Design Defect (Count III)

Count III alleges a design defect under Ohio Revised Code § 2307.75. That statute provides that "a product is defective in design or formulation if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation . . . exceeded the benefits associated with that design or formulation. . . ." Ohio Rev. Code § 2307.75.

Defendant argues that Plaintiff has failed to plead the necessary elements of a product liability claim: "(1) the existence of a defect in the product at issue, (2) that the defect existed at the time the product left the hands of the manufacturer, and (3) the defect was the direct and proximate cause of the plaintiff's injury."

Jones v. Staübli Motor Sports Div. of Staübli Am. Corp., 897 F. Supp. 2d 599, 607 (S.D. Ohio 2012) (Frost, J.). Defendant maintains that the Complaint is devoid of factual allegations concerning how the Product was allegedly defective and how the alleged defect was the direct and proximate cause of his injuries.

The Court rejects this argument. Plaintiff alleges that the Product is defective in design because it uses oxidized zirconium rather than cobalt or titanium. The oxidized zirconium combines metal and ceramic. Plaintiff alleges that the ceramic is weak and brittle and difficult to fabricate into the necessary shapes, causing the Product to have poor shock resistance, be easily damaged and easily wear out. Doc. #3, PageID#77. Plaintiff further alleges that this defect existed when the Product left the hands of the manufacturer, and that it was the direct and proximate cause of his personal injuries. *Id.* at PageID##76, 78.

The Court concludes that Plaintiff has stated a plausible claim of a design defect under Ohio Revised Code § 2307.75. Defendant's Motion to Dismiss Count III is OVERRULED.

3. Manufacturing Defect (Count IV)

Count IV of the Complaint alleges a manufacturing defect under Ohio Revised Code § 2307.74. The statute provides that "[a] product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units

manufactured to the same design specifications, formula, or performance standards." Ohio Rev. Code § 2307.74.

Although Plaintiff generally alleges that the Product "deviated from manufacturing standards when it came off the production line," and that it "failed to perform in its intended manner," resulting in Plaintiff's injuries, he fails to identify what the manufacturing defect is. Defendant argues that Plaintiff has failed to state a plausible claim for relief.

Citing *Jones*, 897 F. Supp. 2d at 610, Plaintiff argues that a manufacturing defect may be inferred from the Product's unsafe, unexpected performance. In *Jones*, however, there was evidence of a specific manufacturing defect. As designed, a socket in a race car re-fueling system should have disengaged when the plaintiff released the handle, but it did not. *See id.* In contrast, Plaintiff has not alleged how the Product implanted in his knee deviated from any manufacturing standards.

Plaintiff also cites to *Creech v. Emerson Climate Techs., Inc.*, No. 3:15-cv-14, 2015 U.S. Dist. LEXIS 147087, at *8 (S.D. Ohio Oct. 28, 2015) (Rice, J.), in which this Court noted that, even though plaintiff had not yet identified a specific manufacturing defect, details concerning the exact nature of such a defect are typically in the defendant's exclusive control, making them difficult to ascertain prior to discovery. Nevertheless, in *Creech*, the Court granted leave to amend because the plaintiff had already hired an expert witness who opined that a manufacturing defect existed.

The Court agrees with Defendant that Plaintiff's allegations of a manufacturing defect are simply too conclusory to state a plausible claim under Ohio law. The Complaint contains no factual allegations to support a claim that the Product implanted in Plaintiff deviated in a material way from Defendant's design specifications or performance standards, or from otherwise identical units manufactured to the same design specifications or performance standards. *See, e.g., Frey*, 642 F. Supp. 2d at 795 (dismissing manufacturing defect claim where plaintiffs did "nothing more than provide a formulaic recitation of the elements of a claim under the statute" and "failed to allege any facts that would permit the Court to conclude that a manufacturing defect occurred and that the defect was the proximate cause of [the] alleged injuries.").

The Court therefore SUSTAINS Defendant's Motion to Dismiss Count IV, but dismisses this claim without prejudice. Given that the Court is already giving Plaintiff the opportunity to amend his Complaint to assert an OPLA claim under Ohio Revised Code § 2307.77 (product defective due to nonconformance with manufacturers' representations), the Court will likewise give Plaintiff the opportunity to amend his manufacturing defect claim within 14 days, if he can do so within the bounds of Fed. R. Civ. P. 11.

4. Failure to Warn (Count V)

Count V of the Complaint asserts a claim of failure to warn under Ohio Revised Code § 2307.76(A). That statute provides:

(A) Subject to divisions (B) and (C) of this section, a product is defective due to inadequate warning or instruction if either of the following applies:

(1) It is defective due to inadequate warning or instruction at the time of marketing if, when it left the control of its manufacturer, both of the following applied:

- (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
- (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

(2) It is defective due to inadequate post-marketing warning or instruction if, at a relevant time after it left the control of its manufacturer, both of the following applied:

- (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
- (b) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Ohio Rev. Code § 2307.76(A).

Plaintiff alleges that, despite knowing of the defective condition of the Product, Defendant failed to adequately warn the medical community and consumers about the risks associated with the use of the Product. Plaintiff further alleges that, if he had received an adequate warning, he would not have used the Product and would not have suffered harm. Doc. #3, PageID##82-85.

Defendant cites to the “learned intermediary” doctrine, codified in Ohio Revised Code § 2307.76(C):

An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

Ohio Rev. Code § 2307.76(C). This “learned intermediary” doctrine has been extended to warnings about medical devices. *Vaccariello v. Smith & Nephew Richards, Inc.*, 94 Ohio St. 3d 380, 384, 763 N.E.2d 160, 164 (2002).

Defendant maintains that Plaintiff’s claim is subject to dismissal because he failed to plead how the warning given was inadequate for his physician, what warnings were provided to his physician, what different warning to his physician would have been appropriate or adequate, and whether the physician had any independent knowledge of the risks associated with the Product.

The Court disagrees. Under Ohio law, the “learned intermediary” doctrine is a defense to a failure-to-warn claim. *Boyd v. Lincoln Elec. Co.*, 179 Ohio App.3d 559, 2008-Ohio-6143, 902 N.E.2d 1023, at ¶53. Because a plaintiff is “not required to plead around all potential defenses,” dismissal at this stage would be premature. *See McDaniel v. Upsher-Smith Labs., Inc.*, 893 F.3d 941, 950-51 (6th Cir. 2018) (Cole, C.J., concurring in part and dissenting in part). Accordingly, the Court **OVERRULES** Defendant’s Motion to Dismiss Count V.

C. Punitive Damages (Count XII)

Plaintiff also seeks punitive damages. Defendant argues that because an award of punitive damages is derivative, and all other counts are subject to dismissal, this claim must be dismissed as well. Given that some of Plaintiff’s claims survive the Motion to Dismiss, the Court **OVERRULES** Defendant’s Motion to Dismiss Count XII.

IV. Conclusion

For the reasons set forth above, the Court **SUSTAINS IN PART** and **OVERRULES IN PART** Defendant Smith & Nephew, Inc.’s Motion to Dismiss Plaintiff’s Complaint. Doc. #5.

The Court **DISMISSES WITH PREJUDICE** Plaintiff’s claims of negligence (Count I), fraudulent misrepresentation (Count VIII), fraudulent concealment (Count IX), negligent misrepresentation (Count X) and unjust enrichment (Count XI), because they are abrogated by the OPLA. Although Plaintiff’s claims of

breach of express and implied warranty (Counts VI and VII) are also abrogated by the OPLA, they are DISMISSED WITHOUT PREJUDICE. Within 14 days of the date of this Decision and Entry, Plaintiff is given leave to amend his Complaint to replead these claims under the OPLA if he can do so within the bounds of Fed. R. Civ. P. 11.

Although Plaintiff has failed to state a plausible claim of a manufacturing defect under the OPLA (Count IV), the Court DISMISSES this claim WITHOUT PREJUDICE. Again, within 14 days of the date of this Decision and Entry, Plaintiff may amend his Complaint to cure the insufficiencies discussed above, but only if he can do so within the strictures of Fed. R. Civ. P. 11.

The Court SUSTAINS Defendant's Motion to Dismiss the claim of supplier liability under the OPLA (Count II) and DISMISSES this claim WITH PREJUDICE.

The Court OVERRULES the Motion to Dismiss the OPLA claims of design defect (Count III) and failure to warn (Count V). The Court also OVERRULES the Motion to Dismiss the claim for punitive damages (Count XII).

To summarize, subject to the filing of an Amended Complaint on those claims dismissed herein without prejudice, Plaintiff may proceed on his claims of design defect (Count III), manufacturing defect (Count IV), failure to warn (Count V), breach of express warranty (Count VI), breach of implied warranty (Count VII) and punitive damages (Count XII).

A handwritten signature in black ink, appearing to read "Walter H. Rice".

Date: September 2, 2020

WALTER H. RICE
UNITED STATES DISTRICT JUDGE